DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 28 1988

Re: Ucephan
Docket No. 88E-0104

#10

The Honorable Donald J. Quigg
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Quigg:

This is in regard to the application for patent extension for U.S. Patent No. 4,284,647, filed by Kendall-McGaw Laboratories, Inc. under 35 U.S.C. et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Ucephan, the human drug product claimed by the patent.

The total length of the review period for Ucephan is 2,871 days. Of this time, 2,058 occurred during the testing phase and 813 occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: February 14, 1980. The applicant claims the letter date, January 10, 1980, as the effective date of the first investigational new drug application (IND) related to the approved product. However, FDA records indicate that IND 17-123 became effective 30 days after receipt, on February 14, 1980.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: October 2, 1985. The applicant claims the letter date, September 30, 1985, as the date that the NDA was initially submitted. However, FDA records indicate that FDA did not receive NDA 19-530 until October 2, 1985.

3. The date the application was approved: December 23, 1987. FDA has verified the applicant's claim that NDA 19-530 was approved on December 23, 1987.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Donald J. Bird
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